

IN THE UNITED STATES DISCTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

POLYMER TECHNOLOGY SYSTEMS,
INC.

Plaintiff,

v.

ROCHE DIAGNOSTICS CORPORATION,
ROCHE DIAGNOSTICS GMBH, ROCHE
DIAGNOSTICS OPERATIONS, INC.,
ROCHE OPERATIONS LTD

Defendants.

1 : 10-cv- 0061 LJM -TAB

CIVIL ACTION NO. _____

DEMAND FOR JURY TRIAL

FILED
U.S. DISTRICT COURT
INDIANAPOLIS DIVISION
10 JAN 15 PM 4:38
SOUTHERN DISTRICT
OF INDIANA
LAURA A. BRIGGS
CLERK

COMPLAINT

Plaintiff, Polymer Technology Systems, Inc., (hereinafter "PTS"), presents this Complaint for a declaratory judgment and damages against Defendants, Roche Diagnostics Corporation, Roche Diagnostics GmbH, Roche Diagnostics Operations, Inc., and Roche Operations LTD. (hereinafter "Defendants"), and PTS states as follows:

PARTIES

1. PTS is a corporation organized under the laws of the State of Indiana and having its principal place of business at 7736 Zionsville Road, Indianapolis, Indiana 46268. PTS is in the business of researching, developing, manufacturing, and selling point-of-care diagnostic products for the human healthcare market.

2. Defendant Roche Diagnostics GmbH ("RDG") is a corporation organized under the laws of Germany and having its principal place of business at Sandhofer Strasse 116, D-68298 Mannheim, Germany.

3. Defendant Roche Diagnostics Corporation ("RDC") is a corporation organized under the laws of the State of Indiana and having its principal place of business at 9115 Hague Road, Indianapolis, Indiana 46256.

4. Defendant Roche Diagnostics Operations, Inc. ("RDO") is a corporation organized under the laws of the State of Indiana and having its principal place of business at 9115 Hague Road, Indianapolis, Indiana 46256.

5. Defendant Roche Operations LTD. ("ROL") is a corporation organized under the laws of the Bermuda and having its principal place of business at 2 Church Street Clarendon House, Hamilton, Bermuda. According to United States Patent and Trademark Office assignment records, ROL has designated Woodard, Emhardt, Moriarty, McNett & Hen at 111 Monument Circle, Indianapolis, IN 46204 as its correspondent.

NATURE OF THE ACTION

6. This is an action by PTS for declaratory relief under 28 U.S.C. §§ 2201 *et seq.*

7. There is an actual, immediate, and justiciable controversy that exists within the jurisdiction of this Court under 28 U.S.C. § 1338 as to the scope, infringement, and validity of U.S. Patent No. 5,366,609 ("the '609 patent"). A copy of the '609 patent is attached as Exhibit A.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.* Subject matter jurisdiction is properly founded under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court retained jurisdiction over this matter as stated in the Stipulated Final Judgment entered in the case styled *Roche Diagnostics Corp. and Roche Diagnostics*

GmbH v. Polymer Technology Systems, Inc., No. 1:03-CV-0848 JDT-WTL ("the 2003 litigation"). The Stipulated Final Judgment is attached as Exhibit B. This Court has personal jurisdiction over Defendants RDC, RDG, RDO, and ROL pursuant to the laws of the state of Indiana and the United States Constitution, including the Indiana long-arm statute Ind. Trial Rule 4.4(A), and the Due Process Clause of the Fifth Amendment. RDC and RDO are entities organized under the laws of Indiana and each maintains its principal place of business in Indiana. General personal jurisdiction exists over RDC and RDG because they maintain systematic and continuous contacts with Indiana and within this district at least as a result of their product sales in Indiana and interactions with PTS in Indiana. In addition, at least specific personal jurisdiction exists over RDO and ROL based on their residence or Indiana correspondent designated under 35 U.S.C. § 293 and based on their substantial contacts with this Court in relation to the '609 patent. For at least these reasons, the exercise of jurisdiction over RDC, RDG, RDO, and ROL does not offend traditions of fair play and substantial justice.

10. Venue in this Court is proper under 28 U.S.C. §§ 1391 and 28 U.S.C. § 1400(b).

THE PATENT CONTROVERSIES

11. PTS is a small, local Indiana company. PTS employs 75 people in Indianapolis, and nearly twice that if you count suppliers, consultants and contract workers. PTS has approximately four hundred investors, most of which are Indianapolis, Indiana residents. PTS is a vital part of the local economy and was recently ranked as one of the 5,000 fastest growing private companies in America.

12. Upon information and belief, Defendants are part of a large international conglomerate based in Germany. Defendants have significant market power in the area of blood diagnostics.

13. The '609 patent issued November 22, 1994 and is assigned to RDO and ROL.

14. Defendants are no strangers to asserting the '609 patent. In the 2003 litigation, RDG and RDC sued PTS in this Court, alleging that PTS' meters infringe the '609 patent. The 2003 litigation was part of Defendants' pattern of suing small companies over the '609 patent and other patents and leaving such small companies with the Hobson's choice of enduring the expense of patent litigation or entering into an onerous license agreement. PTS entered into such a license agreement and entered into a Stipulation of Dismissal of the 2003 litigation.

15. In 2004, RDC, RDO, and Corange International Limited (which later changed its name to ROL) sued Apex Biotechnology Corp., Hypoguard USA, Inc., Medline Industries, Inc., and Home Diagnostics, Inc. in this Court ("the Home Diagnostics litigation") for infringement of the '609 patent and other patents. In the Home Diagnostics litigation, this Court entered an order construing the various claim terms of the '609 patent. The claim construction order is attached as Exhibit C. Based on this claim construction, this Court entered summary judgment of non-infringement of the '609 patent in favor of Home Diagnostics. The Court's order granting summary judgment is attached as Exhibit D. Other Roche patents asserted in the Home Diagnostics litigation were found unenforceable due to inequitable conduct. RDC, RDO, and Corange International Limited quickly settled their case against the other defendants.

REDACTED

16. On April 16, 2009, PTS received a letter from RDG and RDC concerning the '609 patent license agreement. This License Agreement is part of the Settlement Agreement between RDC and RDG that settled the 2003 litigation. This Court retained jurisdiction over Settlement Agreement. This RDG and RDC letter makes clear that the real dispute is not over the parties' license agreement, but whether the PTS meter infringes the '609 patent. This letter is attached as Exhibit E.

17. In the letter, RDC and RDG state that "Roche is in possession of reports and other documents which show that at least the CardioChek PA and the CardioChek produced by PTS continue to make literal use of at least one claim of U.S. Patent No. 5,366,609 ("609 Patent")". RDC and RDG also demanded royalties under the Agreements on test strips made by PTS, even though none of the claims of the '609 patent cover such test strips.

18. In response to the April 16, 2009 letter, PTS informed RDC and RDG that it sells no products covered by the '609 patent and that the '609 patent is invalid. The Ketosite/Stat-Site system (K 911801) has been sold in the United States since at early as 1991 by GDS Technology of Elkhart, Indiana. This analyzer was described in a public submission for clearance to the FDA that was granted in July 1991. This system includes both a Test Card and a Test Module, which is a pluggable memory key containing the test parameters. Since the priority date of the '609 patent is June 8, 1993, the Ketosite/Stat-Site system is prior art to the '609 patent.

19.

REDACTED

REDACTED

20.

21. Based on the construction of the '609 patent entered by the Court in the Home Diagnostics litigation, PTS makes or sells no products covered by the '609 patent.

REDACTED

22. RDC and RDG employed methods that are unfair and against public policy in obtaining the Agreements. Specifically, RDC and RDG threatened PTS with expensive litigation that RDC and RDG knew would force PTS, a small local start-up company, into bankruptcy due to the cost of the litigation. Therefore, PTS was coerced into signing the Agreements.

23.

REDACTED

To make matters

worse, Defendants continue to assert the '609 patent even though it knows that PTS does not infringe.

24. Based on the constructions of the '609 patent entered by the Court in the Home Diagnostics litigation, Defendants are collaterally estopped from relitigating the meaning of the '609 patent claim terms.

25.

REDACTED

ACTUAL CASE OR CONTROVERSY

26. PTS reasonably apprehends it will be sued for infringement of the '609 patent at least because:

- a. RDC and RDG have claimed via the April 16, 2009 letter that "Roche is in possession of reports and other documents which show that at least the CardioChek PA and the CardioChek produced by PTS continue to make literal use of at least one claim of the '609 patent.
- b. RDC and RDG have previously sued PTS under the '609 patent for the manufacture, sale or use of different products.

COUNT I – Patent Invalidity

27. PTS re-alleges and incorporates by reference paragraphs 1-26.
28. There is an actual controversy as to the validity of the '609 patent.
29. The '609 patent is invalid because of failure to meet one or more conditions of patentability prescribed by 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT II – Patent Non-Infringement

30. PTS re-alleges and incorporates by reference paragraphs 1-29.
31. There is an actual controversy as to the infringement of the '609 patent.

32. PTS does not infringe any claim of the '609 patent because each and every element of any claim of the '609 patent is not found in any PTS product, including the accused CardioChek and CardioChek PA either literally or under the doctrine of equivalents.

COUNT III – Exceptional Case

33. PTS re-alleges and incorporates by reference paragraphs 1-32.

34. Pursuant to 35 U.S.C. § 285, attorney fees may be awarded to the prevailing party to a patent dispute in exceptional cases.

35. Defendants' assertion of the '609 patent with knowledge that the asserted claim of the '609 patent is not infringed by PTS and is invalid makes this case "exceptional" within the meaning of the statute.

36. Accordingly, PTS is entitled to attorney fees under 35 U.S.C. §285.

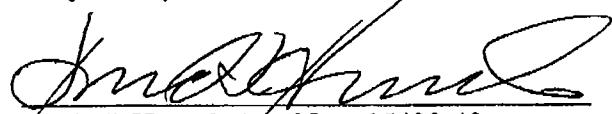
RELIEF REQUESTED

Wherefore, Plaintiff prays for judgment and relief including:

- (A) That the Court enter a judgment declaring the '609 patent invalid;
- (B) That the Court enter a judgment declaring that PTS and PTS' products do not infringe, contribute to the infringement by another, or induce the infringement of, any claims of the '609 patent, either literally or under the doctrine of equivalents;
- (C) An award declaring that the royalties paid to Roche should be reimbursed with interest;
- (D) An award declaring this case exceptional pursuant to 35 U.S.C. § 285 and granting Plaintiff its attorney fees in pursuing this case; and
- (E) Such other and further equitable relief as this Court may deem just and proper.

Dated this 15th day of January, 2010.

Respectfully submitted,



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